

### **REMARKS**

Applicants submit, contemporaneously herewith, a Request for Continued Examination pursuant to 37 C.F.R. §1.114.

Claims 1, 3, 4, 8-19, and 21-26 are pending. Claims 1, 3, 4, 8-16, and 21-24 have been rejected. Claims 17-19 and 25 are allowed. Claim 26 has been added.

### **Claim Rejections - 35 U.S.C. §112**

The Examiner rejected independent Claims 8 and 21 as well as Claims 9-16, 22, and 23 which depend therefrom, respectively, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response to the Examiner's rejection, Applicants have amended independent Claims 8 and 21 to call for, *inter alia*, "the sleeve being positionable between the male and female portions to provide a separation between the male and female portions to prevent the male and female portions from locking together..." It is Applicants belief that this amendment clarifies the subject matter regarded as Applicants invention, specifically, that the sleeve separates the male and female portions when in use. In view of these amendments, Applicants respectfully request removal of the 35 U.S.C. §112 rejection.

### **Claim Rejections - 35 U.S.C. §102**

Claims 1, 3, and 4 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,607,560 to Pfaff et al. ("Pfaff '560").

Pfaff '560 discloses joint prostheses 1, as shown in Fig. 1, including shaft 2 and spherical head 3. Spherical head 3 has a conical bore 4 which receives cone 5 of shaft 2 therein. Positioned between and securing cone 5 of shaft 2 to conical bore 4 of spherical head 3 is coupling element 6. By utilizing coupling element 6, the uniform "transfer of force between the cone and the spherical head" is achieved. Pfaff '560, col. 1, lines 61-62. Additionally, Pfaff '560 discloses that coupling element 6 may have a structure "like that of a woven fabric" and may be fixed in position by epoxy resin. Pfaff '560, col. 2, line 23; col. 2, lines 64-67.

Independent Claim 1 calls for the combination of a sleeve and a modular orthopaedic implant including, *inter alia*, a first component with a female junction element and a second component with a male junction element receivable within the female junction element to couple

the components together, and a hollow, resilient sleeve *capable of being rolled upon itself into a ring-like configuration*, the sleeve having an outer portion engageable with the female junction element and an inner portion engageable with the male junction element.

Having thoroughly reviewed the disclosure of Pfaff '560, nowhere does Pfaff '560 disclose or suggest a *hollow, resilient sleeve capable of being rolled upon itself into a ring-like configuration*. The relevant disclosure in Pfaff '560 is that coupling element 6 may have a structure like that of a woven fabric. However, Pfaff '560 goes on to disclose that such a structure is formed from a biocompatible metal, metal alloy, or carbon. Pfaff '560, col. 2, lines 45-63. Nowhere does Pfaff '560 disclose the dimensions of the threads forming the "fabric" of coupling element 6 or any physical properties of the threads. Further, Pfaff '560 discloses that "to facilitate production of a coupling element in the correspondingly desired form, it is advantageous if the threads or the layers of threads are fixed in their position by means of a fixing agent," such as epoxy resin. Pfaff '560, col. 2, line 64-col. 3, line 2. By "fixing" the threads with an epoxy resin, coupling element 6 would be a rigid, fixed object, which would be incapable of being rolled upon itself into a ring-like configuration. Thus, Pfaff '560 fails to disclose or suggest that coupling element 6 is "capable of being rolled upon itself into a ring-like configuration," as required by independent Claim 1.

For the foregoing reasons, Applicants respectfully submit that amended independent Claim 1, as well as Claims 3 and 4 which depend therefrom, are not anticipated by Pfaff '560.

New Claim 26 depends from independent Claim 1 and calls the combination of a sleeve and a modular orthopaedic implant of Claim 1, wherein *the female junction interacts directly with the male junction to couple the components together*.

In contrast to Claim 26, Pfaff '560 fails to disclose or suggest a modular orthopaedic implant having a first component with a female junction element and a second component with a male junction element receivable within the female junction element, and a hollow resilient sleeve, wherein the female junction interacts directly with the male junction to couple the components together. Specifically, coupling element 6 of Pfaff '560 is used to create a force fit connection between conical bore 4 of spherical head 3 and cone 5 of shaft 2. Moreover, even if cone 5 of shaft 2 was inserted within conical bore 4 of spherical head 3, cone 5 would fail to contact the wall forming conical bore 4 in a manner sufficient to couple the components together, as required by amended independent Claim 1.

Advantageously, the present invention provides for a sleeve which can be inserted between corresponding male and female tapers of an orthopaedic component, i.e., self-locking tapers, to *temporarily maintain the components in an assembled arrangement*. Application Serial No. 10/749,483, [0014]; *see* [0013]. The use of the sleeve between corresponding tapers prevents damage to the components, allows for easy removal and exchange of trial components, and may provide sufficient friction to hold the parts together during trial fitting. *Id.* at [0013]-[0015]. Then, after the trial fitting has concluded, the sleeve can be removed and the male and female tapers of the orthopedic component engaged to lock the same together.

For the foregoing reasons, Applicants respectfully submit that amended Claim 26, which depends from independent Claim 1, is not anticipated by Pfaff '560.

Claims 8, 10, 14, 21, and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,428,579 to White ("White '578").

White '578 discloses modular prosthesis 10 having stem 12, body 14, and sleeve 16 for affixing stem 12 and body 14 together. *See* White '578, col. 4, lines 28-30. The invention of White '578 "employs a distinctive geometry and connection technology that variably locks together the three fundamental components 12, 14 and 16 of the prosthetic hip 10 into a fixed configuration." Col. 4, lines 50-54.

Amended independent Claims 8 and 21 each call for, *inter alia*, a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion, the male portion and female portion *being directly engageable in self-locking taper relationship* to couple the components together, and a hollow resilient sleeve.

As discussed in detail above, White '578 utilizes sleeve 16, which is necessary to lock stem component 12 and body component 14 together. Thus, the device disclosed in White '578 does not include a first component with a male junction element and a second component with a female junction element, the male portion and female portion being directly engageable in self-locking taper relationship to couple the components together, and a sleeve. Further, even if sleeve 16 was taken to be the first component with a male junction element having a tapered male portion and body 14 was taken to be the second component with a female junction element having a tapered bore corresponding to the male portion, the modular prosthesis of White '578

would lack a sleeve in addition to a first component and a second component, as required by independent Claims 8 and 21.

For the foregoing reasons, Applicants respectfully submit that amended independent Claims 8 and 21, as well as Claims 10, 14, and 23, which depend therefrom, respectively, are not anticipated by White '578.

Claims 8, 10, 13, 14, 16, 21, and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,921,500 to Averill et al. ("Averill '500").

Averill '500 discloses femoral stem 12 including post 18 and ceramic femoral hip component 30 having socket 32 with inner seating surface 34. Inner seating surface 34 of socket 32 is tapered at a taper which is steeper than the taper provided along the outer seating surface 26 of post 18. Averill '500, col. 4, lines 30-34. To facilitate the connection between inner seating surface 34 and outer seating surface 26 adapter 40 is provided.

As discussed above, Averill '500 utilizes adapter 40, which is necessary to lock stem 12 and socket 32 together. Thus, the device disclosed in Averill '500 fails to disclose a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion, *the male portion and female portion being directly engageable in self-locking tapered relationship to couple the components together* and a hollow resilient sleeve having an outer portion engageable with the female portion and inner portion engageable with the male portion, and a sleeve, as called for in independent Claim 8 and 21. For the same reasons as discussed above with respect to White '578, if adaptor 40 of Averill '500 was taken to be one of the first component or the second component called for in independent Claims 8 and 21, Averill '500 would then lack a sleeve, in addition to a first component and a second component, as required by independent Claims 8 and 21.

For the foregoing reasons, Applicants respectfully submit that amended independent Claims 8 and 21, as well as Claims 10, 13, 14, 16, and 23 which depend therefrom, are not anticipated by Averill '500.

Claims 8, 10, 13, 14, 16, 21, and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,080,679 to Pratt et al. ("Pratt '679").

Pratt '679 discloses, as shown in Fig. 3, prosthesis 23 having outer tapered wall 45 which forms a self-locking taper fit with tapered walls 43 of sleeve 19. The exterior surface of sleeve

19 is complementary to interior walls 43 of ball member 25 to secure sleeve member 19 to ball member 25.

In contrast to the limitations of amended independent Claims 8 and 21, as set forth above, Pratt '679 discloses prosthesis 23 having tapered wall 45 engageable with ball 25 only through mutual engagement with sleeve 19. Thus, Pratt '679 fails to disclose a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion, the male portion and female portion being directly engageable in self-locking tapered relationship to couple the components together and a hollow resilient sleeve having an outer portion engageable with the female portion and inner portion engageable with the male portion, as called for in independent Claim 8 and 21. Further, for the same reasons as discussed above with respect to White '578, even if sleeve 19 of Pratt '679 was taken to be one of the first component or the second component called for in independent Claims 8 and 21, Pratt '679 would then lack a sleeve, in addition to a first component and a second component, as further required by independent Claims 8 and 21.

For the foregoing reasons, Applicants respectfully submit that independent Claims 8 and 21, as well as Claims 10, 13, 14, 16, and 23, which depend therefrom, are not anticipated by Pratt '679.

Claims 8-11, 14, 16, 21, and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,108,452 to Fallin ("Fallin '452"). Similar to Averill '500 discussed in detail above, Fallin '452 discloses prosthesis body 11 having a frusto-conically shaped neck 14. Neck 14 is configured to be connected to neck extension sleeves 45 via interaction of neck 14 and conical inner surface 47. Extension sleeves 45 further include conical outer surface 46 configured to engage socket 28 of head 27.

For at least the reasons set forth above with respect to Averill '500, Applicants respectfully submit that independent Claims 8 and 21, as well as Claims 10, 11, 14, 16, and 23 which depend therefrom, are not anticipated by Fallin '452.

**Claim Rejection - 35 U.S.C. §103(a)**

Claim 12 is rejected under 35 U.S.C. §103(a) as being obvious over Pratt '679 in view of U.S. Patent Application No. 2002/0116068 to McLean ("McLean '068"). To form this rejection,

the Examiner relies on Pratt '679 for disclosing all the limitations of amended independent Claim 8, from which Claim 12 depends. For the reasons set forth above, Pratt '679 fails to disclose or suggest each and every limitation of amended independent Claim 8. The Examiner's additional citation of McLean '068 does not overcome this deficiency as McLean '068 fails to disclose or suggest a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion, the male portion and female portion being directly engageable in self-locking tapered relationship to couple the components together and a hollow resilient sleeve having an outer portion engageable with the female portion and inner portion engageable with the male portion, and a sleeve, as called for in independent Claim 8 and 21. Thus, for the foregoing reasons, Applicants respectfully submit that Claim 12, which depends from amended independent Claim 8, is not obvious over Pratt '670 in view of McLean '068.

Claim 15 is rejected under 35 U.S.C. §103(a) as being obvious over White '578 in view of McLean '068. To form this rejection, the Examiner relies on White '578 for disclosing the limitations of amended independent Claim 8, from which Claim 15 depends. For the reasons set forth above, White '578 does not disclose or suggest each and every limitation of amended independent Claim 8. As set forth above, the Examiner's additional citation of McLean '068 does not overcome this deficiency, as McLean '068 fails to disclose or suggest a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore corresponding to the male portion, the male portion and female portion being directly engageable in self-locking taper relationship to couple the components together, and a hollow resilient sleeve, as required by amended independent Claim 8. Thus, for the foregoing reasons, Applicants respectfully submit that dependent Claim 15, which depends from amended independent Claim 8, is not obvious over White '578 in view of McLean '068.

Claims 1, 3, 4, and 24 are rejected under 35 U.S.C. §103(a) as being obvious over Fallin '452 in view of Pfaff '560. In forming this rejection, the Examiner relied on Fallin '452 for disclosing all the elements of amended independent Claim 1, except for a hollow resilient sleeve capable of being rolled upon itself into a ring-like configuration. Applicants are in agreement with the Examiner that Fallin '452 fails to disclose or suggest a hollow resilient sleeve capable of being rolled upon itself into a ring-like configuration. However, for the reasons set forth above

with respect to Pfaff '560, Applicants respectfully submit that Pfaff '560 also fails to disclose or suggest a hollow resilient sleeve capable of being rolled upon itself into a ring-like configuration. Thus, the Examiner's additional citation of Pfaff '560 fails to overcome the admitted deficiency of Fallin '452. Thus, for the reasons set forth above with respect to Fallin '452 and Pfaff '560, neither Fallin '452 nor Pfaff '560, either alone or in combination, disclose or suggest a first component with a female junction element and a second component with a male junction element receivable within the female junction element to couple the components together, and a hollow resilient sleeve capable of being rolled upon itself into a ring-like configuration. Therefore, Applicants respectfully submit that amended independent Claim 1, as well as Claims 3, 4, and 24, which depend therefrom, are not obvious over Fallin '452 in view of Pfaff '560.

Claim 24 is rejected under 35 U.S.C. §103(a) as being obvious over Pfaff '560 in view of Fallin '452. In forming this rejection, the Examiner relies on Pfaff '560 as disclosing all the limitations of amended independent Claim 1. For the reasons set forth above with respect to Fallin '452 and Pfaff '560, neither Fallin '452 nor Pfaff '560, either alone or in combination, disclose or suggest a first component with a female junction element and a second component with a male junction element receivable within the female junction element, and a hollow resilient sleeve capable of being rolled upon itself into a ring-like configuration. Thus, for the reasons set forth above, Applicants respectfully submit that Claim 24, which depends from amended independent Claim 1, is not obvious over Pfaff '560 in view Fallin '452.

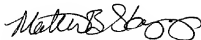
It is believed that the above represents a complete response to the Official Action and reconsideration is requested. Specifically, Applicants respectfully submit that the application is in condition for allowance and respectfully requests allowance thereof.

In the event Applicants have overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby petition therefore and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Should the Examiner have any further questions regarding any of the foregoing, she is respectfully invited to telephone the undersigned at (260) 424-8000.

Application Serial No. 10/749,483  
Amendment After Final dated January 18, 2007  
Reply to Office Action dated October 19, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Matthew B. Skaggs", with a stylized flourish at the end.

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